REMARKS

I. INTRODUCTION

This communication is submitted in response to the Office Action dated July 25, 2005. Claims 1, 23, 29 and 51 have been amended. Claims 1, 2, 4, 6-30, 32 and 34-56 remain in the application. Reconsideration of the application, as amended, is respectfully requested.

II. AMENDMENTS TO THE CLAIMS

Applicants' attorney has made amendments to the claims as indicated above. These amendments were made solely for the purpose of clarifying the language of the claims, and do not introduce new matter. Entry of these amendments is respectfully requested.

Claim 1 has been amended to clarify the limitations previously introduced upon the cancellation of original claim 5. These limitations required the calculation of a slope of a line fit to the series of physiological characteristic values in the most recent of the values is within a qualifying range. Inherent in these limitations is a determination of whether a most recent of the series of physiological characteristic values is within the qualifying range. This latter feature is now explicitly recited as a separate wherein clause in amended claim 1.

III. EXAMINER INTERVIEW

Record is made of a telephonic interview with Examiner Natnithithadha, Applicant's attorney Ajit Narang, and Applicant's undersigned attorney Karen Canady, held on October 5, 2005. During this interview, the above-indicated amendment to claim 1 was reviewed and discussed. Applicants have amended all of the independent claims accordingly and with a good faith intention to place the application in condition for allowance. Should the Examiner disagree, the courtesy of a telephone call to Applicant's undersigned attorney would be most appreciated.

IV. PRIOR ART REJECTIONS

In paragraph (4) of the Office Action, claims 1, 2, 6-9, 11, 13-15, 23, 25, 27, 28-30, 34-37, 39, 41-43, 51-53, 55, and 56 were rejected under 35 U.S.C. §102(b) as being anticipated by Say et al. (Say), U.S. Patent No. 6,175,752. In paragraph (5) of the Office Action, claims 4, 16, 17, 19-22, 32,

44-46, and 48-50 were rejected under 35 U.S.C. §103(a) as being unpatentable over Say in view of Mault et al. (Mault), U.S. Publication No. 2003/0208113. In paragraph (6) of the Office Action, claims 10, 12, 18, 26, 38, 40, 46, and 54 were rejected under 35 U.S.C. §103(a) as being unpatentable over Say in view of Houben et al. (Houben), U.S. Patent No. 6,572,542. Applicants respectfully traverse these rejections.

Claim 1 was amended with the Amendment submitted on May 6, 2005, to incorporate all of the limitations of canceled claims 3 and 5; and claim 29 was amended to incorporate all of the limitations of canceled claims 31 and 33. Applicants maintain that the Patent Office has failed to establish that the prior art teaches or suggests each element of these claims. More specifically, the Examiner's attention is directed to the conditional features of the dynamic characteristic monitor of the invention.

Independent claims 1 and 29 are generally directed to a physiological characteristic monitor that comprises an input device capable of receiving a signal from a sensor, the signal being based on a sensed physiological characteristic value of a user; and a processor for analyzing the received signal; wherein the processor determines a dynamic behavior of the physiological characteristic value; and wherein the processor provides an observable indicator based upon the dynamic behavior of the physiological characteristic value so determined; wherein analyzing the received signal and determining a dynamic behavior includes repeatedly measuring the physiological characteristic value to obtain a series of physiological characteristic values and analyzing a rate of change of the physiological characteristic value over time from the series of physiological characteristic values; determining whether a most recent of the series of physiological characteristic values is within a qualifying range; and wherein **a slope of a line fit to the series of physiological characteristic values is calculated if the most recent of the series of physiological characteristic values is within the qualifying range**. Independent claims 23 and 51 are directed to similar features, except wherein the most recent of the series of physiological characteristic values exceeds a threshold value.

These dynamic characteristic monitoring embodiments are discussed at pages 15-21, paragraphs 53-75 (and Figures 3A-3D) of the specification. This portion of the specification describes advantages achieved by the invention for anticipating a glucose crash, detecting inadequate nocturnal basal rate, anticipating hyperglycemic incidents, and maximizing athletic performance as

examples of means of anticipating a dangerous physiological event. These uses take advantage of the claimed feature wherein the alarm is not based simply on a threshold value or on a threshold change in slope of the dynamically monitored value. Instead, as exemplified in Figures 3A-3D, the slope of the line fit to the series of physiological characteristic values is calculated IF a most recent of the series of values is within a qualifying range. This provides valuable information with less inconvenience to the user.

The cited references do not teach nor suggest these various elements of Applicants' independent claims.

Say merely describes an analyte monitor that includes a sensor, a sensor control unit, and a display unit. The sensor has, for example, a substrate, a recessed channel formed in the substrate, and conductive material disposed in the recessed channel to form a working electrode. The sensor control unit typically has a housing adapted for placement on skin and is adapted to receive a portion of an electrochemical sensor. The sensor control unit also includes two or more conductive contacts disposed on the housing and configured for coupling to two or more contact pads on the sensor. A transmitter is disposed in the housing and coupled to the plurality of conductive contacts for transmitting data obtained using the sensor. The display unit has a receiver for receiving data transmitted by the transmitter of the sensor control unit and a display coupled to the receiver for displaying an indication of a level of an analyte. The analyte monitor may also be part of a drug delivery system to alter the level of the analyte based on the data obtained using the sensor.

The portion of Say cited by the Examiner as a basis for the rejection of claims 1, 2, 6-9, 11, 13-15, 23, 25, 27, 28-30, 34-37, 39, 41-43, 51-53, 55 and 56, does not in fact teach or suggest the conditional aspect of Applicants' claims. The portion of Say relied upon by the Examiner, column 51, lines 29-36, discusses an alarm system activated when the rate or acceleration of an increase or decrease in analyte level reaches or exceeds a threshold value. However, Say lacks any discussion about using a slope of a line fit to the series of physiological characteristic values that is calculated if a most recent of the series of physiological characteristic values meets or exceeds a particular criterion. Instead, Say teaches away from Applicants' invention because it teaches indicating a hyperglycemic or hypoglycemic condition is likely to occur simply when the rate or acceleration of increasing or decreasing analyte levels occur. Say contains no suggestion or

motivation to modify this approach by making the calculation of a slope of a line fit to the series of physiological characteristic values conditional on the level of a most recent of the series of physiological characteristic values.

Mault merely describes a system for assisting a person to maintain a blood glucose level between predetermined limits that comprises an electronic device, which comprises a display, a clock, a memory, and a processor; and a software program executable by the processor of the electronic device, adapted to receive nutritional data of food consumed by the person, adapted to calculate the blood glucose level for the person using the nutritional data and a glycemic response model for the person, and further adapted to present the blood glucose level to the person on the display of the electronic device. Like Say, Mault lacks any discussion about making the calculation of a slope of a line fit to the series of physiological characteristic values conditional on the level of a most recent of the series of physiological characteristic values.

Houben merely describes information derived from ECG signals and EEG signals that may be employed in combination to reliably predict the onset, or to indicate the presence of, hypoglycemia in a human patient. In one embodiment, ECG and EEG signals are processed and the information derived from them is combined to determine whether a patient suffering from diabetes is undergoing a hypoglycemic event, or whether such an event is imminent. Input data from the patient or a health care provider may also be used to increase the accuracy and reliability of the system. Detection of a hypoglycemic event by the system can result in the output of an alarm signal and/or the delivery or administration of a beneficial agent such as insulin, glucagon or diazoxide to the patient. The system may be implantable, external, or a combination of external and implantable components. The control strategy of the present system is preferably microprocessor based and/or implemented using dedicated electronics. In another embodiment, the glycemic state of the patient is continuously or relatively continuously monitored and controlled by the system. The system may contain any of a number of different types of feedback control systems for monitoring the glycemic state of a patient and controlling same, such as fuzzy logic systems, adaptive systems, reinforcement learning systems, and the like. However, like Say and Mault, Houben lacks any discussion about making the calculation of a slope of a line fit to the series of physiological characteristic values conditional on the level of a most recent of the series of physiological characteristic values.

Even when combined, the references provide no teaching, motivation or suggestion to make the calculation of a slope of a line fit to the series of physiological characteristic values conditional on the level of a most recent of the series of physiological characteristic values, by first determining whether a most recent of the series of values is within a qualifying range. Moreover, the various elements of Applicants' claimed invention together provide operational advantages over Say, Mault, and Houben. In addition, Applicants' invention solves problems not recognized by Say, Mault, and Houben.

Thus, Applicants submit that independent claims 1, 23, 29 and 51 are allowable over Say, Mault, and Houben. Further, the dependent claims are submitted to be allowable over Say, Mault, and Houben in the same manner, because they are dependent on these independent claims, and thus contain all the limitations of the independent claims. In addition, the dependent claims recite additional novel elements not shown by Say, Mault, and Houben.

IV. CONCLUSION

In view of the above, it is submitted that this application is now in good order for allowance and such allowance is respectfully solicited. Should the Examiner believe minor matters still remain that can be resolved in a telephone interview, the Examiner is urged to call Applicants' undersigned attorney.

Respectfully submitted,

GATES & COOPER LLP
Attorneys for Applicant(s)

Howard Hughes Center
6701 Center Drive West, Suite 1050
Los Angeles, California 90045
(310) 641-8797

Date: October 10, 2005

By: _____
Name: Karen S. Canady
Reg. No.: 39,927

KSC/bjs/mrj